

LABORATORY CERTIFICATION STANDARDS REVIEW COUNCIL
MEETING MINUTES FROM 8/14/97

Attendance

Staff: Jack Sullivan, Mike Kvitrud, Alfredo Sotomayor and Jeff Ripp

Council Members: Mary Christie (Chair), Gilbert Williams (Vice-chair), David Kollakowsky, Ruth Klee Marx, Bill Sonzogni, Debbie Cawley and Russ Janeshek

Guests: Barb Burmeister (SLH), Laura Forst (DATCP), Paul Harris (Davy Labs)

Action Item Summary

- The previous meeting's minutes were accepted.
- The SDWA reference sample variance requests were approved as stated in the July 21, 1997 letter from the Chair.
- The Council wanted to wait until they reviewed a draft of the changes to NR 149 before a recommendation was given.
- The Council requested that the meeting agendas and minutes to be published on the WWW.

Agenda Items

- I. Approval of April 9, 1997 Meeting Minutes
 - A. The Council suggested that the action items should be emphasized and/or summarized at the beginning.
 - B. **A motion was made to accept the April 9, 1997 meeting minutes, it was seconded and the minutes were unanimously accepted.**

- II. Laboratory Certification Program Updates
 - A. Program Status
 1. Performance measures were established for the Program.
 - a. The number of audits per year.
 - b. The time from audit until the report is issued.
 2. The auditors will have closure plans by Sept. 30, 1997 for labs which were audited over three years ago, but did not receive a report. These labs will be evaluated again and new reports issued.
 3. A Council member suggested that the Program publicize the staffing situation (# of auditors, their responsibilities and audits expected) in LabNotes and on the WWW.
 - a. Central office has:
 - 2 LabCert funded full-time commercial, industrial & SDWA auditors.
 - 2 LabCert funded full-time commercial, industrial & SDWA auditors with central and regional audit coordination responsibilities.
 - 1 GPR funded auditor is now assigned to quality assurance for the Department and will not be assigned to audit.
 - 1 LabCert funded full-time regional auditor with administrative responsibilities.
 - 2 LabCert funded administrative LTE's.
 - 1 LabCert funded half-time program assistant vacancy.
 - b. Regional staff includes:
 - 2 full time certification officers with other non-LabCert responsibilities.
 - 3 LTE certification officers.
 4. The original estimate for the Oracle computer system conversion was low. Now BIETA is estimating approximately \$72 K to convert the LabCert computer system. The Program is investigating different ways of building the new system and moving forward with the planning of it. About ½ of the programming hours necessary to complete the system are currently available. The Council wanted to know what NELAC was planning to use for tracking laboratories. NELAC is considering Oracle, but it has limited funds to work with. One consideration in building the LabCert Program's system is compatibility with the NELAC system and standards.

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B. Regional (Registered) Auditing Program

1. A map was distributed showing who will be responsible for auditing each county.
2. The Western Central Region LTE position will be converted to a half-time FTE position this fiscal year.
3. The regional auditors are having a mock-audit training session at the State Laboratory of Hygiene to help provide consistent auditing throughout the regions. **The Council said this was a good idea and requested that the 2 new central office auditors also attend.**

C. NR 149 Rule Change

1. The Program is minimizing any long-term changes to the code because of the pending major rewrite of NR 149 needed to incorporate the National Certification Program.
2. The timeline of the rule change:
 - a. October 1997 → Go to the NR Board for authorization to hold public hearings
 - b. October 21 - December 19, 1997 → Public comment period
 - c. November 14, 1997 → Public hearing announcement
 - d. December 11 & 12 → Public hearings in Eau Claire, Appleton & Madison
 - e. March 1998 → Go to the NR Board for final approval
 - f. April - May 1998 → Legislative review period
 - g. July 1, 1998 → Rule becomes effective
3. The proposed changes are as follows:
 - a. The following sections are being rewritten for clarification and no substantial changes will be made:
 - Application section [s. NR 149.07]
 - Renewal section [s. NR 149.09]
 - Methods of analysis and sample collection, preservation and holding time section [s. NR 149.11]
 - Reference sample section [s. NR 149.13]
 - b. The requirement to use EPA reference samples for SWDA certification will be removed.
 - c. The authoritative sources section will be updated to include new federal method updates.
 - d. The fee section will be changed to increase the relative value from 24 to 30 RVUs for reciprocity labs and to create separate base fees for certified (15 RVUs) and registered (10 RVUs) labs.
 - e. The minimum fee will waiver for SDWA nitrate only testing will now include fluoride.
 - f. Explosive and Glycol certification will be added into the existing category structure.
 - g. An immunoassay category with a delayed implementation date will be created.
4. **The Council expressed concern over the lack of communication between the Department's monitoring requirement drafters and the laboratory community.** They indicated that laboratories are usually asked to analyze new substances before they actually have the capability to do so. If the labs were notified of new monitoring requirements early, they could have a new method up and running smoothly in about a year.
5. **Some Council members suggested the change in the fee section made such a slight difference that it did not need to be changed.** The Program would like to even the proportion of fees paid vs. workload for certified and registered labs. It does not wish to financially burden small water supply labs which would like to analyze for both nitrate and fluoride. The Program would also like to increase the reciprocity fee to make it more equivalent to what certified labs are assessed.
6. **A Council member inquired whether an "out-of-state" fee could be assessed.** The Program cannot charge more to a lab in another state for the same service(s) because it would interfere with inter-state commerce.
7. **The Council was not against taking the immunoassay issue to public hearing, but had concerns about how immunoassay would be used and who would need to be certified.**
8. **The Council wanted to wait until they reviewed a draft of the changes to NR 149 before a recommendation was given.**

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- III. Lab of the Year Award
- A. Last year 6 nominations were received.
 - B. The 1997 winners were the city of Medford WWTP and the WP&L Edgewater Facility.
 - C. The 1998 nominations are due by December 31, 1997.
 - D. A nomination form was distributed at the meeting.
 - E. The winners will be selected in January and the awards will be presented at the March NR Board meeting.
- IV. Variance Requests
- A. SDWA reference sample variances
 1. The Department received 4 requests from labs wishing to waive the requirement in s. NR 149.21 to analyze EPA Water Supply reference samples for renewal.
 2. A proposal for accepting the variance requests was mailed to the Council for a recommendation.
 3. **The Council was polled prior to the meeting and approved of the variance requests as stated in the July 21, 1997 letter from the Council Chair.**
 4. The 4 variances were granted and the proposed code change includes a long term solution to this situation.
 - B. Fee variance
 1. The Department received 1 variance request from a research laboratory to waive the requirement in s. NR 149.05 to pay application fees.
 2. The variance was not granted because it would be an unfair competitive advantage for the lab.
- V. Council's LabNotes Column and Web Page
- A. The deadline for articles in the fall 1997 issue of LabNotes is September 30, 1997.
 - B. The Council talked about writing an article concerning NELAC in the next issue. (The Program will write a detailed NELAC update.)
 - C. Any ideas for the Council's article should be directed towards the Chair or Vice-chair.
 - D. **The Council requested that the meeting agendas and minutes to be published on the WWW.**
- VI. National Environmental Laboratory Accreditation Conference (NELAC) Presentation
- A. An overview of the conference and standards was given.
 1. Adopting the national standards is a voluntary process.
 2. The national standards are divided into 6 chapters.
 - a. Chapter 1 - National Program Policy & Structure
 - b. Chapter 2 - Performance Evaluation Testing
 - c. Chapter 3 - On-site Assessment Process
 - d. Chapter 4 - Accreditation Process
 - e. Chapter 5 - Quality Assurance and Control Requirements
 - f. Chapter 6 - Accrediting Authority Requirements
 3. The standards were approved and sufficient enough to be adopted by the first group of nine states.
 4. The LabCert Program encouraged the Council to both review the standards themselves and encourage the laboratories they represent to review them.
 5. The assessor's manual is currently in the draft stage.
 6. The on-site assessment checklists are not drafted yet.
 7. NELAP will not meet the needs of all laboratories and limited flexibility will be given to small laboratories. Currently, Wisconsin has a dual accreditation system: Certification for commercial analysis and Registration for in-house analysis. **The Council thought this was going to be the most difficult issue of adopting NELAP.**
 8. The national standards will allow approval for supplemental state requirements such as Wisconsin's DRO and GRO methods, but this will be discouraged.

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9. **A Council member asked whether the LabCert Program needed a legislative sponsor to begin the process of adopting the national standards.** The Program does not need legislative support at this time. The Program needs the Department to take an official position on adopting the national standards before it can begin the process.
- B. The implementation process for the LabCert Program.
 1. The statute may accommodate NELAP*, but NR 149 and ATCP 77*, Wis. Adm. Codes would need to be changed to incorporate the national standards.
 2. Currently, there is no fee for becoming a NELAP accrediting authority, but this may change in the future.
 3. The Program would need to be audited by the national program to become a NELAP accrediting authority.
 4. The Program's auditors would also need to eventually attend training and be tested to become NELAP approved auditors.
- C. The implementation process for laboratories.
 1. A lab's "host" or primary accrediting authority would become the state in which it is located. If that state has not adopted NELAP, then the lab could "shop around" for NELAP certification until the time that its own state becomes a NELAP accrediting authority.
 2. A lab would only be audited by its "host" or primary NELAP accrediting authority and would get certified through reciprocity with other NELAP states.
 3. A lab would still need to be certified (through reciprocity) in each state they do work for and pay each state's fees.

VII. Items Reserved for Future Meetings

- A. The results of the deficiency survey the Council participated in during the last meeting (4/9/97).
- B. The informational paper on the Department's enforcement policy.
- C. The status of NR 148, the proposed data reporting rule.
- D. NELAC adoption and implementation.

VIII. Future Meeting Date

- A. The next LabCert Standards Review Council meeting was tentatively set for Thursday, November 13, 1997.
- B. The focus of the next Council meeting will be the National Certification Program (NELAC).
- C. The Program will work the Chair to set up the next meeting.
- D. The Council members should contact the Chair or Vice-chair to get items on the next meeting's agenda.

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